

902 KAR 20:250. Specialized medical technology services.

RELATES TO: KRS 216B.010-216B.131, 216B.990(1), (2), 311.241-311.247, 311.990

STATUTORY AUTHORITY: KRS 13A.100, 216B.040, 216B.105

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.105 mandates that the Cabinet for Human Resources regulate health facilities and health services. This administrative regulation provides minimum licensure requirements for the operation of specialized medical technologies and services within the Commonwealth.

Section 1. Definitions. (1) "Governing authority" or "licensee" means the individual, agency, partnership, or corporation, in which the ultimate responsibility and authority for the conduct of the institution is vested.

(2) "License" means an authorization issued by the cabinet for the purpose of operating a specialized medical technology service.

(3) "Certified radiation operator" means a person who has been certified pursuant to KRS 211.870 and 902 KAR 105:010 to 105:070 as an operator of sources of radiation.

(4) "Qualified urologist" means a person who is a doctor of medicine or a doctor of osteopathy licensed to practice medicine and surgery and who is board certified or is in the process of being certified by the American Board of Urology or the American Osteopathic Board of Surgery and who otherwise meets criteria established by the specialized medical technology service's governing authority.

(5) "Magnetic resonance imaging (MRI)" means a diagnostic imaging modality which utilizes magnetic resonance, an interaction between atoms and electromagnetic fields, to project images of internal body structures.

(6) "Computed tomography (C.T.) Scanning" means a radiological diagnostic imaging procedure that shows cross sectional images of internal body structures.

(7) "Lithotripter" means a noninvasive treatment technique that utilizes shock waves to shatter kidney stones.

(8) "Licensure agency" means the Division for Licensing and Regulation in the Office of the Inspector General, Cabinet for Human Resources.

(9) "Qualified anesthesiologist" means a person who is a doctor of medicine or a doctor of osteopathy licensed to practice medicine and surgery and who is board certified or in the process of being certified by the American Board of Anesthesiology or the American Osteopathic Board of Surgery and who otherwise meets the criteria established by the specialized medical technology service's governing authority.

Section 2. Scope of Operation and Services. "Specialized medical technologies" describes a particular medical technology service which improves some aspect of diagnosis, therapy or related capability. Advanced technologies are often translated to medical equipment which has a high capital and/or operating cost. For the purpose of this administrative regulation, specialized medical technology services shall be in a fixed/freestanding location or located within a hospital and operated independently from the hospital's governing authority. The following specialized medical technology services include magnetic resonance imaging (MRI), computed tomography (CT) scanning, lithotripters, cardiac catheterization, radiation therapy, x-ray, and other diagnostic imaging services requiring a certificate of need.

Section 3. Administration. (1) Licensee.

(a) The licensee shall be legally responsible for the service and for compliance with federal, state and local laws and regulations pertaining to the operation of the service.

(b) The licensee shall establish lines of authority and designate an administrator who shall be principally responsible for the daily operation of the service.

(2) Policies. The service shall follow written administrative policies covering all aspects of operation, including:

(a) A description of organizational structure, staffing and allocation of responsibility and accountability;

(b) A description of linkages with inpatient facilities and other providers;

(c) Policies and procedures for the guidance and control of personnel performances;

(d) A written program narrative describing in detail the service(s) offered, methods and protocols for service delivery, qualifications of personnel involved in the delivery of the services, and goals of the service(s);

(e) A description of the administrative and patient care records and reports; and

(f) Procedures to be followed in the storage, handling and administration of drugs and biologicals.

(3) Personnel.

(a) The facility shall employ a sufficient number of qualified personnel to provide effective patient care and all other related services. The licensee shall provide written personnel policies which are available to all employees and are reviewed and revised on an annual basis. If the staff/patient ratio does not meet the needs of the patients, the Division of Licensing and Regulation shall determine and inform the program administrator in writing how many additional personnel are to be added and of what job classification, and shall give the basis for this determination.

(b) Medical director. The service shall have a medical director who is a licensed physician responsible for all medical aspects of the service.

(c) There shall be a written job description for each position which shall be reviewed and revised as necessary.

(d) Current personnel records shall be maintained for each employee which include the following:

1. Name, address and Social Security number;

2. Evidence of current registration, certification or licensure of personnel;

3. Records of training and experience; and

4. Records of performance evaluation.

(4) In-service training. All personnel shall participate in ongoing in-service training programs relating to their respective job activities including thorough job orientation for new employees.

(5) Medical records.

(a) The service shall maintain medical records which contain at least the following:

1. Medical or social history, including data obtainable from other providers relevant to the services provided;

2. Name of referring physician and physicians orders for services;

3. Description of each medical visit or contact, to include condition or reason necessitating visit or contact, assessment, diagnosis, services provided, medications and treatments prescribed, and disposition made;

4. Reports of all physical examinations, laboratory, x-ray, and other test findings relevant to the services provided; and

5. Documentation of all referrals made, including reason for referral, to whom patient was referred, and any information obtained from referral source.

(b) Confidentiality of all patient records shall be maintained at all times.

(c) Transfer of records. The service shall follow written systematic procedures to assist in continuity of care where the patient moves to another source of care, and the service shall, upon proper release, transfer medical records or an abstract thereof when requested.

(d) Retention of records. After patient's death or discharge the completed medical record shall be placed in an inactive file and retained for five (5) years or in case of a minor, three (3) years after the

patient reaches the age of majority under state law, whichever is longer.

(e) A specific location shall be designated by the specialized medical technology service for the maintenance and storage of the service's medical records.

(f) Provision shall be made for written designation of specific locations for the storage of medical records in the event the specialized medical technology service ceases to operate because of disaster, or for any other reason. The licensee shall safeguard the record and its content against loss, defacement and tampering.

Section 4. Provision of Services. A licensed specialized medical technology service shall comply with the requirements listed in Sections 3 and 5 of this administrative regulation, and the additional requirements in this section specific to that particular technology or service.

(1) Diagnostic imaging services.

(a) Diagnostic imaging services are those services which produce an image, either through film or computer generated video, of the internal structures of a patient. These services include:

1. MRI;
2. CT scanning;
3. X-ray;
4. Ultrasound;
5. Mammography;
6. Fluoroscopy; and
7. Xerography.

(b) Any specialized medical technology service which provides diagnostic imaging services shall comply with the following:

1. Diagnostic imaging services shall be performed only on the order of a physician, except for mammography services;

2. The services shall prepare a record for each patient to the date of the procedure, name of the patient, description of the procedures ordered and performed, the referring physician, the name of the person performing the procedure, and the date the name of the physician to whom the results were sent;

3. Equipment used for direct patient care shall be fully approved by the Federal Drug Administration (FDA) for clinical use;

4. The service shall follow a written preventive maintenance program to ensure that imaging equipment is operative, properly calibrated, and shielded to protect the operator, patient, environment, and the integrity of the images produced;

5. Imaging services shall have a current license or registration pursuant to applicable Kentucky Statutes and any administrative regulations promulgated thereunder;

6. All personnel engaged in the operation of imaging equipment shall have adequate training and be currently licensed, registered or certified in accordance with applicable state statutes and administrative regulations;

7. There shall be a written training plan for the adequate training of personnel in the safe and proper usage of the imaging equipment;

8. There shall be a physician's verbal order which specifies the reason the procedure is required, the area of the body to be exposed, and the number of images to be obtained and the views needed, which shall be immediately reduced to writing and signed by the physician within forty-eight (48) hours; and

9. There shall be sufficiently trained on duty personnel with adequate equipment to provide emergency resuscitation services in the event of a patient emergency.

(2) Other specialized services. These services include specialized lithotripter services, cardiac catheterization services, and radiation therapy services.

(a) The following standards shall apply to all other specialized services.

1. Other specialized services shall be performed only on the order of a physician;
2. Other specialized services shall be provided under the supervision of a physician who is qualified by advanced training and experience in the use of this specific service offered;
3. Other specialized service shall prepare a record for each patient to include the date of the procedure, name of the patient, description of the procedures ordered and performed, the referring physician, and the name of the person performing the procedure.
4. There shall be a physician's signed order which specifies the reason the procedure is required, the area of the body to be exposed, and the anticipated outcome of treatment;
5. There shall be sufficiently trained on duty personnel with adequate equipment to provide emergency resuscitation services in the event of a patient emergency; and
6. There shall be a written description of procedures to be followed in the event a patient has a medical emergency.
7. There shall be a written training plan utilized to instruct personnel in the safe and proper usage of the equipment.

(b) Specialized lithotripter services. A specialized lithotripter service is a health service which provides for a noninvasive technique for removing kidney or ureteral stones through the use of lithotripter. The following standards shall apply to specialized lithotripter services:

1. Policies. A lithotripter service shall develop patient care policies with the advice of a group of professional personnel that includes at least one (1) qualified urologist and one (1) qualified anesthesiologist. At least one (1) member shall not be a member of the lithotripter service staff. The policies shall include:

- a. A description of how a patient will be transported between the hospital and the lithotripter service;
- b. A description of guidelines for the review and evaluation of the service on an annual basis; and
- c. Policies and protocols governing the utilization and responsibilities of associated hospital staff, if any, in the delivery of lithotripter services;

2. Personnel. The lithotripter service shall employ at least one (1) lithotripter technician, and shall employ or make arrangements with the qualified urologist to be present in the unit during the delivery of lithotripsy services, and one (1) qualified anesthesiologist to be available for procedures requiring anesthesia;

3. Lithotripsy equipment used for direct patient care shall comply with the following:

- a. Lithotripsy equipment shall be fully approved by the Federal Drug Administration (FDA) for clinical use;
- b. The licensee shall follow a written preventive maintenance program to ensure that equipment shall be operative, properly calibrated, properly shielded, and safe for the patient, operator, and environment;
- c. All personnel engaged in the operation of lithotripsy equipment shall have adequate training and be currently licensed, registered or certified in accordance with applicable state statutes and administrative regulations; and
- d. There shall be a written training plan for the adequate training of personnel in the safe and proper usage of the equipment.

(c) Cardiac catheterization services and radiation therapy services. These services shall also comply with the following:

1. The services shall assure that sufficient personnel shall be present to supervise and conduct the services provided, including at least one (1) certified radiation operator, or one (1) physician with specialized training and experience in the area of the services provided.

2. These services shall have a current license, registration or certification pursuant to KRS 211.842 to 211.852 and any administrative regulations promulgated thereunder;

3. There shall be written policies and procedures governing radiologic services and administrative routines that support sound radiologic practices;
4. Reports of interpretations shall be written or dictated and signed by the radiologist or physician;
5. The use of all x-ray apparatus shall be limited to certified radiation operators or physicians. The same limitation shall apply to personnel applying and removing radium element, its disintegration products, and radioactive isotopes;
6. The radiology department shall be free of hazards for patients and personnel. Proper safety precautions shall be maintained against fire, explosion, electrical and radiation hazards;
7. These services shall have a written credentialing and peer review system to ensure that only properly licensed, registered, certified, and trained personnel shall be involved in the delivery of services; and
8. Cardiac catheterization procedures shall be performed by a physician with specific training in the areas of cardiac catheterization.

Section 5. Physical Environment. (1) Accessibility. The facility shall meet requirements for making buildings and facilities accessible to and usable by the physically handicapped pursuant to KRS 198B.260 and administrative regulations promulgated thereunder.

(2) Fire safety. The facility shall be approved by the Fire Marshal's Office before licensure and re-licensure is granted by the licensure agency.

(3) Housekeeping and maintenance services.

(a) Housekeeping. The facility shall maintain a clean and safe facility free of unpleasant odors. Odors shall be eliminated at their source by prompt and thorough cleaning of commodes, urinals, bedpans and other sources.

(b) Maintenance. The premises shall be well kept and in good repair. Requirements shall include:

1. The facility shall insure that the grounds are well kept and the exterior of the building, including the sidewalks, steps, porches, ramps, and fences are in good repair;

2. The interior of the building including walls, ceilings, floors, windows, window coverings, doors, plumbing and electrical fixtures shall be in good repair. Windows and doors shall be screened;

3. Garbage and trash shall be stored in areas separate from those used for the preparation and storage of food and shall be removed from the premises regularly. Containers shall be cleaned regularly;

4. A pest control program shall be in operation in the facility. Pest control services shall be provided by maintenance personnel of the facility or by contract with a pest control company. The compounds shall be stored under lock;

5. Sharp wastes, such as broken glass, scalpel blades, and hypodermic needles, shall be segregated from other wastes and aggregated in rigid disposable containers immediately after use. Needles and syringes shall not be cut, dismantled, or destroyed after use, but shall be placed intact directly into a rigid container. The rigid containers of sharp wastes shall either be incinerated, on site or off site, or disposed of in a sanitary landfill approved pursuant to 401 KAR 47:080.

6. The facility shall establish a written policy for the handling and disposal of all infectious, pathological, and contaminated waste. Any incinerator used for the disposal of waste shall be in compliance with 401 KAR 59:020 or 401 KAR 61:010.

a. Infectious waste shall be placed in double impervious plastic bags and each bag shall be two (2) mils in thickness. A bag, when full, shall not exceed twenty five (25) pounds. All bags shall be securely closed and a tag, which reads "INFECTIOUS WASTE" and identifies the specialized medical technology service from which the waste is being removed and shall be attached to the bag in a conspicuous manner.

b. All unpreserved tissue specimens shall be incinerated on or off site.

c. The following wastes shall be sterilized before disposal or be disposed of by incineration if they

are combustible:

- (i) Dressings and materials from open or contaminated wounds;
- (ii) Waste materials and disposable linens from isolation rooms;
- (iii) Culture plates;
- (iv) Test tubes;
- (v) Sputum cups; and
- (vi) Contaminated sponges and swabs. (14 Ky.R. 1714; Am. 1920; eff. 4-14-88; 18 Ky.R. 862; eff. 10-16-91; TAm eff. 12-10-2012.)